

## **DETAILED ACTION**

### ***Examiner's Response***

Applicant's request for a Pre-Brief Appeal Conference dated 10/29/10 was received and duly noted. The Pre-Brief Appeal Conference resulted in withdrawal of the obviousness rejection over WO 02/055498 - see Office correspondence dated 11/19/10.

In Final Office Action dated 7/30/10, Examiner mistakenly withdrew obviousness-type double patenting rejection over US Application 10/522,208. After reconsideration, Examiner has reinstated the obviousness-type double patenting rejection over US Application 10/522,208 as shown below.

### ***Applicant-Initiated Telephonic Interview***

Examiner held a telephonic interview with Attorney Brittany La on 1/28/11. Attorney La requested by that Examiner reconsider not making the obviousness-type double patenting rejection over US Application 10/522,208 based upon the following remarks:

(1) arguments as set forth by Applicant in regards to obviousness rejection over WO 02/055498; and

(2) the species of in the Specification of 10/522,208 are structurally different from that of the species in the instant application and that the dependent claims of US '208 are drawn to those structurally different species.

Examiner has fully considered Attorney La's remarks; however, those remarks are not persuasive.

Examiner reminded Attorney La that double patenting rejections are based upon a claim by claim comparison between a patent and an application or between two applications - not a comparison of species of the Specification.

In view of this response, the status of the rejections/objections of record is as follows:

### ***Status of the Claims***

Claims 1-4 and 6 are pending and rejected.

Claims 5 and 8-23 have been cancelled.

Claims 7 and 24-38 are directed towards non-elected subject matter.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

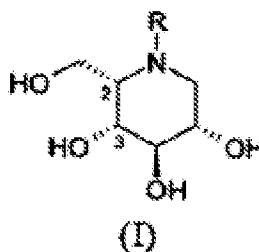
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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 and 13 of copending Application No. 10/522,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

Applicant claims compounds and pharmaceutical compositions of Formula I where R = phenylmethyl wherein the phenyl is substituted by OR<sup>1</sup> substituted on the phenyl at the 4-position wherein R<sup>1</sup> is C<sub>4</sub>-C<sub>5</sub> alkyl - see claim 1 below:

1. (Previously presented) 1. A compound of formula (I) in free or pharmaceutically acceptable salt form:



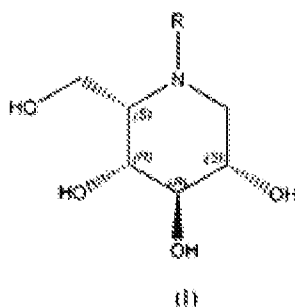
wherein

R is phenylmethyl-, wherein phenyl is substituted by OR<sup>1</sup>; and

R<sup>1</sup> is C<sub>4-5</sub> alkyl.

US 10/522,208 claims compounds of Formula I where R=methylphenyl substituted by OR<sup>1</sup> wherein R<sup>1</sup>=C<sub>1</sub>-C<sub>6</sub> alkyl.

1. (Previously presented) A compound of formula (I) in free or pharmaceutically acceptable salt form:



wherein

R is -C<sub>1-3</sub>alkylAr<sup>1</sup> where Ar<sup>1</sup> is phenyl;

wherein phenyl is substituted by one or more substituents selected from CN, CON(R<sup>3</sup>)<sub>2</sub>, SO<sub>2</sub>R<sup>2</sup>, SO<sub>2</sub>N(R<sup>1</sup>)<sub>2</sub>, N(R<sup>5</sup>)<sub>2</sub>, N(R<sup>3</sup>)COR<sub>2</sub>, N(R<sup>1</sup>)SO<sub>2</sub>R<sup>2</sup>, C<sub>6-6</sub>alkylAr<sup>2</sup>, C<sub>2-6</sub>alkenylAr<sup>2</sup> and C<sub>3-4</sub>alkynylAr<sup>2</sup>

wherein one or more of the -CH<sub>2</sub>- groups of the alkyl chain may be replaced with a heteroatom selected from O, S and NR<sup>3</sup>, provided that when the heteroatom is O, at least two -CH<sub>2</sub>- groups separate it from any additional O atom in the alkyl chain; or two adjacent substituents on the Ar<sup>1</sup> phenyl may together form a fused 5- or 6-membered saturated or unsaturated ring wherein the ring optionally contains 1 or 2 heteroatoms selected from O, S and NR<sup>3</sup> and is optionally substituted by one or more substituents selected from, an oxo group, C<sub>1-6</sub>alkyl and C<sub>6-3</sub>alkylAr<sup>4</sup>;

and the Ar<sup>1</sup> phenyl is optionally substituted by one or more additional substituents selected from F, Cl, Br, CF<sub>3</sub>, OCF<sub>3</sub>, OR<sup>3</sup> and C<sub>1-6</sub>alkyl;

R<sup>3</sup> is H, or C<sub>1-6</sub>alkyl;

US '208's genus claims clearly encompasses the species as claimed by Applicant; therefore, the obviousness double patenting rejection is made.

Applicant is reminded that double patenting rejections are based upon a claim by claim comparison between a patent and an application or between two applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/  
Examiner  
Art Unit 1625

/Janet L. Andres/

Supervisory Patent Examiner, Art Unit 1625